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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P. and
JANSSEN SCIENCES IRELAND UC,

Plaintiffs,

v.

CIPLA LTD. and
CIPLA USA, INC.,

Defendants.

Civ. Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, "Janssen" or "Plaintiffs") for their Complaint against defendants Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla" or "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement by Cipla of U.S. Patent Nos. 7,700,645 B2 ("the '645 Patent") and 8,518,987 B2 ("the '987 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. and for a declaratory judgment of infringement

of U.S. Patent No. 7,126,015 B2 ("the '015 Patent"), and U.S. Patent No. 7,595,408 B2 ("the '408 Patent") under 35 U.S.C. §§ 1 et seq., 28 U.S.C. §§ 2201 and 2202. This action arises out of Cipla's filing of Abbreviated New Drug Application ("ANDA") No. 206288 seeking approval with the United States Food and Drug Administration ("FDA") to sell generic versions of Plaintiffs' highly successful PREZISTA® (darunavir) 800 mg tablets prior to the expiration of the patents owned by Janssen.

THE PARTIES

2. Plaintiff Janssen Products, L.P. is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

3. Plaintiff Janssen Sciences Ireland UC is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. On information and belief, Cipla Ltd. is a corporation organized under the laws of India, maintaining its headquarters at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400 013, India. On information and belief, Cipla Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Cipla USA, Inc.

5. On information and belief, Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9100 S. Dadeland Blvd, Suite 1500, Miami, FL 33156. On information and belief, Cipla USA, Inc. is in the business of, among other things, of marketing and selling generic versions of branded

pharmaceutical products for the U.S. market. Cipla USA, Inc. is a wholly-owned subsidiary of Cipla Ltd.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

7. On information and belief, this Court has personal jurisdiction over Cipla Ltd. because Cipla Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Cipla Ltd. has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products or active pharmaceutical ingredients ("APIs") for pharmaceutical products that are sold in this judicial district.

8. On information and belief, this Court has personal jurisdiction over Cipla USA, Inc. because Cipla USA, Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Cipla USA, Inc. has had persistent and continuous contacts with this judicial district, including developing, marketing and/or selling pharmaceutical products that are sold in this judicial district.

9. On information and belief, Cipla Ltd., directly and/or through Cipla USA, Inc., markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

10. On information and belief, Cipla Ltd. derives substantial revenue from selling generic pharmaceutical products and/or APIs used in various generic pharmaceutical products sold throughout the United States, including in this judicial district.

11. On information and belief, Cipla USA, Inc. acts as the agent of Cipla Ltd., and has submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of Cipla Ltd.

12. On information and belief, Cipla USA, Inc. has registered to distribute drugs in New Jersey by applying for and obtaining a Wholesale Drug & Medical Device Registration from the State of New Jersey Department of Health.

13. On information and belief, Cipla Ltd. and Cipla USA, Inc. operate and act in concert as an integrated, unitary business. For example, Cipla Ltd. includes within its Annual Report the activities of Cipla USA, Inc., including its capital and reserves.

14. Cipla also has engaged in New Jersey-related activities in connection with its efforts to obtain FDA approval to market its generic version of PREZISTA®. In connection with its efforts to obtain FDA approval to market its generic version of PREZISTA®, Cipla USA, Inc. sent Paragraph IV letters to Janssen in New Jersey, advising Janssen of its contention that certain patents covering Prezista are invalid and/or not infringed by Cipla's 800 mg Generic Tablets. If Cipla succeeds in obtaining FDA approval, it would sell its generic version of PREZISTA® in New Jersey and other states, causing injury to Janssen in New Jersey.

15. Cipla has stipulated and/or consented to personal jurisdiction in prior patent cases, including in the related consolidated action, *Janssen Prods, L.P., et al v. Lupin Ltd., et al*, 10-Civ-5954 D.N.J. (WHW) (CLW) ("the Related Action"). *See also e.g.*, *Astrazeneca et al v. Ivax Corp. et al.*, 08-Civ-4993, D.N.J. (JAP) (TJP); *Prometheus Labs., Inc. v. Roxane Labs.,*

Inc. et al, 11-Civ-01241 (FSH) (PS); *Merck, Sharp & Dohme Corp., et al. v. Cipla USA, Inc., et al,* 13-Civ-04017 (JBS) (AMD).

16. In the Related Action, Cipla provided discovery as if it were a party in connection with Janssen's complaint against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva") for infringement of the '645, '015 and '408 Patents. It produced documents, witnesses and information in the Related Action. Cipla had access to Janssen's infringement and validity contentions and interrogatories for the '645, '015 and '408 Patents. Cipla's counsel also had access to the confidential electronic docket, including all Orders and filings. Cipla participated in hearings and its counsel attended trial held in March 2014.

17. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

18. On April 20, 2010, the United States Patent and Trademark Office ("the PTO") issued the '645 Patent, entitled "Pseudopolymorphic Forms of a HIV Protease Inhibitor." A true and correct copy of the '645 Patent is attached hereto as Exhibit A.

19. Plaintiff Sciences Ireland UC holds title to the '645 Patent.

20. The '645 Patent expires on December 26, 2026.

21. The FDA has awarded 6 months of pediatric exclusivity for PREZISTA® (darunavir). The period of pediatric exclusivity applicable to the '645 Patent does not expire until June 26, 2027.

22. On August 27, 2013, the PTO issued the '987 Patent, entitled "Pseudopolymorphic forms of a HIV protease inhibitor." A true and correct copy of the '987 Patent is attached hereto as Exhibit B.

23. Plaintiff Sciences Ireland UC holds title to the '987 Patent.

24. The '987 Patent expires on February 16, 2024.

25. The period of pediatric exclusivity applicable to the '987 Patent does not expire until August 16, 2024.

26. Janssen Products L.P. is the holder of approved New Drug Application ("NDA") No. 21-976 for PREZISTA®.

27. PREZISTA® is included in FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

28. The FDA's "Orange Book" also lists patents associated with approved drugs. The '645 and '987 Patents are listed in the "Orange Book" in association with PREZISTA®. The claims of the '645 and '987 Patents cover PREZISTA®.

29. On October 24, 2006, the PTO issued the '015 Patent, entitled "Method for the Preparation of Hexahydro-furo-[2,3-b]furan-3-ol." A true and correct copy of the '015 Patent is attached hereto as Exhibit C.

30. Janssen Sciences Ireland UC holds title to the '015 Patent.

31. The '015 Patent expires on June 21, 2023.

32. On September 29, 2009, the PTO issued the '408 Patent, entitled "Methods for the Preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol." A true and correct copy of the '408 Patent is attached hereto as Exhibit D.

33. Janssen Sciences Ireland UC holds title to the '408 Patent.

34. The '408 Patent expires on May 6, 2025.

35. The '015 and '408 Patents claim processes useful for the preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol ("bis-THF"), an essential component of darunavir.

36. On information and belief, Cipla has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 and '408 Patents prior to their expiration.

37. On information and belief, Cipla's preparations include, but are not limited to, the development of generic versions of PREZISTA® 800 mg tablets ("Cipla's Generic 800 mg Tablets") and the filing of an ANDA with a Paragraph IV certification.

38. On information and belief, Cipla intends to use processes claimed in the '015 and '408 Patents to prepare the bis-THF in Cipla's Generic 800 mg Tablets.

39. The bis-THF is incorporated into and present in the drug substance (darunavir) in Cipla's Generic 800 mg Tablets.

40. The bis-THF in Cipla's Generic 800 mg Tablets is intact and without material change from the bis-THF resulting from Janssen's patented processes.

41. The bis-THF resulting from Janssen's patented processes is an essential component of Cipla's Generic 800 mg Tablets.

42. On information and belief, Cipla Ltd., itself and/or through its subsidiary, agent and alter ego, Cipla USA, Inc., submitted ANDA No. 206288 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of Cipla's Generic 800 mg Tablets.

43. On information and belief, Cipla Ltd. and Cipla USA, Inc. collaborated in the research, development, preparation and filing of ANDA No. 206288 for Cipla's Generic 800 mg Tablets.

44. On information and belief, Cipla USA, Inc. is Cipla Ltd.'s authorized U.S. agent for ANDA No. 206288.

45. On information and belief, Cipla USA, Inc. will market and/or distribute Cipla's Generic 800 mg Tablets if ANDA No. 206288 is approved by the FDA.

46. On information and belief, Cipla USA, Inc. participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 206288.

47. On or about March 2, 2015, Plaintiffs received a letter dated February 26, 2015 ("the Cipla Paragraph IV Letter") stating that Cipla had amended ANDA No. 206288 to seek approval to manufacture, use and sell Cipla's Generic 800 mg Tablets prior to the expiration of the '645 and '987 Patents.

48. The Cipla Paragraph IV Letter also states that the Cipla ANDA No. 206288 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '645 Patent will not be infringed by the commercial manufacture, use and sale of Cipla's Generic 800 mg Tablets and that the claims of the '987 Patent are invalid.

49. In the Cipla Paragraph IV Letter, Cipla stated the '645 Patent will not be infringed under the doctrine of equivalents for reasons that the court considered and rejected in the Related Action.

50. On information and belief, Cipla had actual and constructive notice of the court's Opinion and Order addressing the same legal arguments as in the Cipla 800 mg Paragraph IV Letter.

51. In the Cipla Paragraph IV Letter, Cipla did not dispute that the claims of the '645 Patent are valid.

52. In the Cipla Paragraph IV Letter, Cipla did not dispute that the commercial manufacture, use and sale of Cipla's Generic 800 mg Tablets would infringe the claims of the '987 Patent.

53. In the Cipla Paragraph IV Letter, Cipla also did not dispute that the claims of the '987 patent were neither anticipated nor obvious. Instead, it stated only that the claims of the '987 Patent were invalid for lack of written description and/or enablement under 35 U.S.C. § 112. During prosecution of the '987 Patent, the PTO considered and rejected the same § 112 arguments.

54. On information and belief, Cipla had actual and constructive notice of the '645, '987, '015 and '408 Patents prior to the filing of ANDA No. 206288.

55. On information and belief, Cipla has made, and continues to make substantial preparation in the United States to manufacture, offer to sell, sell and/or import Cipla's Generic 800 mg Tablets prior to the expiration of the '645, '987, '015 and '408 Patents.

56. On information and belief, Cipla's actions include, but are not limited to, the development of Cipla's Generic 800 mg Tablets and the filing of an ANDA with a Paragraph IV certification.

57. On information and belief, Cipla Ltd. and Cipla USA, Inc. continue to seek approval of ANDA No. 206288 from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of Cipla's Generic 800 mg Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 206288.

58. Plaintiffs commenced this action within forty-five days of the date they received Cipla's Paragraph IV Notice of ANDA No. 206288 containing the Paragraph IV certifications.

COUNT I

Infringement of the '645 Patent by Cipla Under 35 U.S.C. § 271(e)(2)(A)

59. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 58 above, as if fully set forth here.

60. Under 35 U.S.C. § 271(e)(2)(A), Cipla has infringed the '645 Patent, either literally or under the doctrine of equivalents, by submitting ANDA No. 206288 with a Paragraph IV certification and seeking FDA approval of ANDA No. 206288 to market Cipla's Generic 800 mg Tablets prior to the expiration of the '645 Patent.

61. Cipla's Paragraph IV Letter does not dispute that the claims of the '645 Patent are valid.

62. Cipla had actual and constructive notice of the '645 Patent prior to filing ANDA No. 206288.

63. Plaintiffs have no adequate remedy at law to redress the infringement by Cipla.

64. Plaintiffs will be irreparably harmed if Cipla is not enjoined from infringing or actively inducing or contributing to infringement of the '645 Patent.

COUNT II

Infringement of the '987 Patent by Cipla Under 35 U.S.C. § 271(e)(2)(A)

65. Plaintiffs repeat and reallege each and every allegation contained in

paragraphs 1 through 64 above, as if fully set forth here.

66. Under 35 U.S.C. § 271(e)(2)(A), Cipla has infringed the '987 Patent, either literally or under the doctrine of equivalents, by submitting ANDA No. 206288 with a Paragraph IV certification and seeking FDA approval of ANDA No. 206288 to market Cipla's Generic 800 mg Tablets prior to the expiration of the '987 Patent.

67. Cipla's Paragraph IV Letter does not dispute that Cipla's Generic 800 mg Tablets infringe the claims of the '987 Patent.

68. Cipla had actual and constructive notice of the '987 Patent prior to filing ANDA No. 206288.

69. Plaintiffs have no adequate remedy at law to redress the infringement by Cipla.

70. Plaintiffs will be irreparably harmed if Cipla is not enjoined from infringing or actively inducing or contributing to infringement of the '987 Patent.

COUNT III

Declaratory Judgment of Infringement by Cipla of the '015 Patent Under 35 U.S.C. § 271(g)

71. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1-70 hereof, as if set forth fully herein.

72. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Cipla regarding infringement of the '015 Patent.

73. Cipla has made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 Patent prior to its expiration.

74. Cipla's actions, including, but not limited to, the filing of ANDA No. 206288 and systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 206288, indicate a refusal to change its course of action.

75. Any importation into the United States and/or use, offer for sale, and/or sale in the United States of Cipla's Generic 800 mg Tablets will constitute infringement of the '015 Patent under 35 U.S.C. § 271(g).

76. On information and belief, Cipla's had actual and constructive notice of the '015 Patent and Plaintiffs' validity and infringement contentions for the '015 Patent prior to the filing of ANDA No. 206288 seeking approval of Cipla's Generic 800 mg Tablets.

77. On information and belief, Cipla's infringement of the '015 Patent is willful.

78. Plaintiffs are entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Cipla's Generic 800 mg Tablets will constitute infringement of the '015 Patent under 35 U.S.C. § 271(g).

79. Plaintiffs have no adequate remedy at law to redress infringement by Cipla.

80. Plaintiffs will be irreparably harmed if Cipla is not enjoined from infringing or actively inducing or contributing to infringement of the '015 Patent.

COUNT IV

Declaratory Judgment of Infringement by Cipla of the '408 Patent Under 35 U.S.C. § 271(g)

81. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1-80 hereof, as if set forth fully herein.

82. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Cipla regarding infringement of the '408 Patent.

83. Cipla has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '408 Patent prior to its expiration.

84. Cipla's actions, including, but not limited to, the filing of ANDA No. 206288 and systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 206288, indicate a refusal to change its course of action.

85. Any importation into the United States and/or use, offer for sale, and/or sale in the United States of Cipla's Generic 800 mg Tablets will constitute infringement of the '408 Patent under 35 U.S.C. § 271(g).

86. On information and belief, Cipla's had actual and constructive notice of the '408 Patent and Plaintiffs' validity and infringement contentions for the '408 Patent prior to the filing of ANDA No. 206288 seeking approval of Cipla's Generic 800 mg Tablets.

87. On information and belief, Cipla's infringement of the '408 Patent is willful.

88. Plaintiffs are entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Cipla's Generic 800 mg Tablets will constitute infringement of the '408 Patent under 35 U.S.C. § 271(g).

89. Plaintiffs have no adequate remedy at law to redress infringement by Cipla.

90. Plaintiffs will be irreparably harmed if Cipla is not enjoined from infringing or actively inducing or contributing to infringement of the '408 Patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that Cipla has infringed the '645 and '987 Patents under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Cipla's ANDA No. 206288 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the period of pediatric exclusivity applicable to the '645 and '987 Patents;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 206288 would constitute infringement of the '645 and '987 Patents, or inducing or contributing to such conduct, by Cipla pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Cipla and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 206288 until the day after the expiration of the period of pediatric exclusivity applicable to the '645 and '987 Patents;

(e) a judgment declaring that importing, offering to sell, selling, or using the generic darunavir tablets described in ANDA No. 206288 would constitute infringement of the '015 and '408 Patents, or inducing or contributing to such conduct, by Cipla pursuant to 35 U.S.C. § 271(g);

(f) a declaration that Cipla's infringement of the '015 and '408 Patents is willful;

(g) a judgment permanently enjoining Cipla and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially importing, offering to sell, selling, or using the generic darunavir tablets described in ANDA No. 206288 until after the expiration of the '015 and '408 Patents;

(h) a declaration that this case is exceptional;

(i) an award of Plaintiffs' costs, expenses, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(j) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

s/ John E. Flaherty

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Dated: April 9, 2015

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. The matter in controversy is related to the subject matter of:

- *Janssen Products L.P., et al. v. Cipla Ltd., et al.*, Civil Action No. 14-cv-05093-WHW-CLW (D.N.J.);
- *Janssen Products L.P., et al. v. Cipla Ltd., et al.*, Civil Action No. 14-cv-01056-SLR (D. Del.);
- *Janssen Products L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 10-cv-05954-WHW-CLW (D.N.J.);
- *Janssen Products L.P., et al. v. Hetero Drugs, Ltd., et al.*, Civil Action No. 13-cv-01444-WHW-CLW (D.N.J.);
- *Janssen Products L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 13-cv-03891-WHW-CLW (D.N.J.); and
- *Janssen Products L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 14-cv-01370-WHW-CLW (D.N.J.).

Respectfully submitted,

*s/*John E. Flaherty

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